REMARKS

Reconsideration of the rejections set forth in the Office Action dated June 19, 2006, is respectfully requested. Claims 1-14 remain pending.

35 U.S.C. § 112

Claims 46-51 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Examiner has alleged that the current specification fails to explicitly disclose "a mass that is detectable by at least two imaging methods; predetermined time periods for which the marker remains at the site; and the use of MRI and ultrasound to detect the marker."

Applicants respectfully assert that claims 46-51 in fact comply with the enablement requirement. "The test for enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) According to MPEP § 2164.01, "[a] patent need not teach, and preferably omits, what is well known in the art."

With respect to disclosure of "a mass that is detectable by at least two imaging methods," Applicants respectfully assert that this property is inherently in the materials described in the present application. Foerster describes the marker element as being "preferably comprised of a ... substantially radiopaque material." (See page 9, lines 16-17) Applicants respectfully assert that one skilled in the art would be able to make and use "a mass that is detectable by at least two imaging methods" given the disclosure of marker elements comprising a "substantially radiopaque material." According to MPEP § 2164.04, "[a] specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In support of this position, the

Examiner stated, in describing Nash, that "the disclosure of a radiopaque material inherently discloses the ability to remotely image the marker using x-ray and/or fluoroscopy." Accepting this statement as accurate, Applicants' description of radiopaque material means that Applicants have described and enabled markers that are detectable by at least two imaging methods.

With respect to disclosure of "predetermined time periods for which the marker remains at the site," Foerster states that the marker elements could be made of "biodegradable polymers ..., as long as they are biocompatible and visible using an imaging system." (Page 23, lines 4-6) Applicants respectfully assert that a marker made of biodegradable material would inherently remain at the site for a predetermined time period. Therefore, one skilled in the art would be able to make and use a detectable mass that remains at the site for predetermined time periods based on the description of biodegradable polymers.

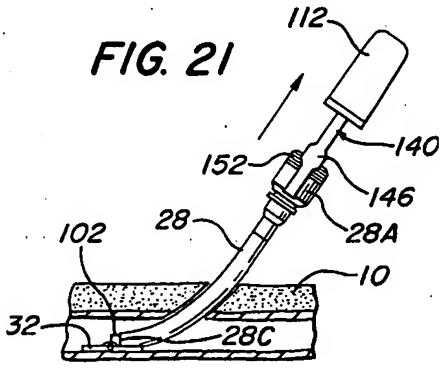
With respect to disclosure of "the use of MRI and ultrasound to detect the marker," Applicants respectfully assert that this property is inherently disclosed. As stated previously, Foerster describes the marker element as being "preferably comprised of a ... substantially radiopaque material." (See page 9, lines 16-17) Applicants respectfully submit that radiopaque materials necessarily have the ability to be remotely imaged using x-ray and/or fluoroscopy. Additionally, Foerster describes known imaging systems as including x-ray, ultrasound, or magnetic resonance imaging (MRI). (See Page 3, lines 12-16) Foerster further states that "The markers should be easy to deploy and easily detected using state of the art imaging techniques." (Page 6, lines 6-7) Radiodense materials are also described that are "highly visible by mammographic imaging. ... During subsequent imaging procedures, they would function to denote the location of the previous biopsy for reference purposes." (Page 22, line 23 - Page 23, line 1) Based on this disclosure, one skilled in the art would be able to make and use a marker that was detectable by MRI and ultrasound. Therefore, Applicants respectfully request withdrawal of the rejections and reconsideration of the claims.

Art Rejections

Claims 46-51 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Nash et al. (USP 5,411,520).

Applicants respectfully assert that Nash does not teach or suggest a marker for marking a cavity site, as required by the claims. Claim 46 specifies that the marker is "for marking a cavity site within the body of a mammalian patient from which a tissue has been removed." Similarly, claim 51 specifies that the marker is "for marking a cavity site from which a tissue sample has been removed." A cavity is defined as a "an unfilled space within a mass; especially a hollowed-out space." (www.m-w.com) In contrast, Nash describes a method for sealing a percutaneous puncture in a blood vessel. (See Abstract; see also Col. 5, lines 59-63 "The sealing member is in the form of an elongated rod-like plug, e.g., a hemostatic resorbable material such as a collagen sponge or foam. This member is arranged for sealing the puncture tract 24A.") As seen in Figs. 21 and 27 below, the implant is being inserted into a puncture tract that extends through the vessel wall. Nash is not concerned with marking a cavity because the puncture tract is not an unfilled space within a mass, i.e., formed by the removal of a portion of tissue. The puncture tract is in fluid communication with the vessel lumen. In fact, Nash's implant was specifically designed for use in a puncture tract that extended all the way through the vessel wall. In addition to the anchoring member 32 that engages the inner surface of the artery (see Col. 13, liens 31-33), the implant includes a spacer in order to ensure "that no portion of the collagen plug 30 will enter the artery (where it could conceivably break off and flow distally)." (Col. 14, lines 19-22)

FIG. 21



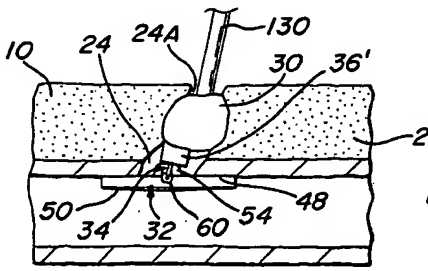


FIG. 27

Therefore, Applicants respectfully assert that the cited reference does not teach or suggest all of the limitations of the pending claims.

For all the reasons stated above, Applicants respectfully request withdrawal of the rejections and reconsideration of the claims as amended. Claims 47-50 depend from claims 46 and are therefore patentably distinct for the same reasons as stated above.

Favorable action on the merits of the claims is therefore earnestly solicited. If any issues remain, please contact Applicant's undersigned representative at (949) 760-9600. The Commissioner is hereby authorized to charge any additional fees that may be required to Deposit Account No. 50-2862.

Respectfully submitted,
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